K051437

1 of 2

AUG 3 - 2005

510(k) SUMMARY
CML™

§807.92(a)(1)

Submitted By	Jim Coombes ICU Medical, Inc. 951 Calle Amanecer San Clemente, CA 92673 949-366-3571
Contact Person	Jim Coombes Quality Engineer
Date of Summary Preparation:	May 23, 2005

§807.92(a)(2)

Trade Name:	CML™
Common Name:	Closed Male Luer
Classification Name:	Intravascular administration set (21 CFR 880.5440)

§807.92(a)(3)

Legally Marketed Substantially Equivalent Device:	Clave Connector K970855

§807.92(a)(4)

Description of Device:	The Closed Male Luer is a normally closed two-way luer activated valve. Within the housing of the Closed Male Luer is a spring-loaded poppet whose head is flush with the male luer of the device. The poppet has an outer diameter that is smaller than the inner diameter of the housing. O-rings are positioned between the housing and poppet that form a physical seal between the poppet and the inner wall of the housing. The fluid pathway is opened when a female luer engages the male luer of the

K051437
2.12

device. The female luer will push the poppet from its normally closed position, allowing fluid to flow freely to the female luer. The device at this stage is considered in the "open position". With the device in the open position, fluids can be injected or withdrawn. The O-rings maintain contact with the inner wall of the housing and the poppet at all times preventing fluid from flowing past the O-rings. Once the female luer connector is removed from the device, the spring-loaded poppet is allowed to return to the "closed position".

§807.92(a)(5)

Intended Use:

The CML is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve device intended for use as an accessory to Intravascular Administration Set. The CML provides access for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter (which is inserted into the vein or artery).

§807.92(a)(6)

Summary of Technological Characteristics

Characteristic Compared	CML	Clave Connector
Product Labeling	See Directions for Use, Sterile, Do Not Reuse, No Latex	See Directions for Use, Sterile, Do Not Reuse, No Latex
Intended Use	Intended for use as an accessory to intravascular administration set	Intended for use as an accessory to intravascular administration set
Design	One piece design activated by luer connection to allow fluid flow	One piece design activated by luer connection to allow fluid flow
Materials	Hard plastic housing, fluid path. Silicone seal, silicone spring retention, liquid silicone lubricant	Hard plastic housing, fluid path. Silicone seal, silicone spring compression, liquid silicone lubricant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 - 2005

Mr. Jim Coombes
Quality Engineer
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K051437
Trade/Device Name: CML 1000
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: May 24, 2005
Received: June 1, 2005

Dear Mr. Coombes:

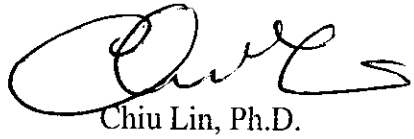
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051437

Device Name: CML ™

Indications For Use: The CML™ is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve device intended for use as an accessory to intravascular administration set. The CML provides access for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter (which is inserted into the vein or artery).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AON
5/3/2006

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051437